Job Title	**:**	**Clinical Research Site Leader**
Department	:	Research Department
Reports to	:	Head of Research
Location	:	Ndevana Community Research Site
Annual salary range	:	R737,796 – R1,009,077

(Please note that the salary range mentioned is indicative only. The offer to the successful candidate will be determined within this salary range, based on the candidate's relevant qualifications and experience).

Purpose of the position:

The clinical research site leader is responsible for providing administrative and operational oversight for the implementation of multiple clinical trials at the site. Key responsibilities include site management, stakeholder collaboration, staff supervision, meeting study deliverables, reporting, maintaining standard operating procedures (SOPs), and supporting team development.

Scope of work:

<u>Project Management</u>

- Oversight and implementation of multiple studies according to established timelines, ensuring compliance with GCP, protocol, SOPs, sponsor requirements and internal quality standards.
- Standardise systems and processes across studies for study planning, implementation, activation, recruitment, enrollment, data cleaning and close out.
- Monitor the progress of all studies and ensure that all protocol and performance targets are met.
- Prepare progress reports for stakeholders, including funders.
- Work with the study Principal investigators to ensure that corrective actions for internal and external monitoring reports are completed within specified timeframes.
- Ensure the proper maintenance of clinical trial essential documents and Investigator Site Files.
- Attend community and stakeholder meetings and present on new studies and on progress of current studies.
- Contribute to the development and review of standard operating procedures as needed

Site Management:

- Ensure that the clinic facility is fully operational in terms of staff and study requirements daily.
- Allocate staff across multiple studies to optimise site performance and ensure balanced workloads.
- Regularly evaluate site staff performance, capacity, and resources to identify staffing or training gaps.
- Initiate recruitment processes promptly when additional resources are required, ensuring the efficient hiring of qualified staff to support new and/or ongoing studies.
- Serve as the primary contact for sponsors and other key stakeholders.
- Contribute to study feasibility assessments by providing accurate information regarding site capabilities, patient demographics, and logistical preparedness.

Staff training and mentorship:

- Supervise and mentor site staff to ensure high standards of research conduct.
- Provide site-level training and retraining as needed, based on quality control and assurance feedback, as well as outcomes from monitoring visits.
- Provide guidance and support to staff in preparing scientific publications, abstracts, and presentations.
- Ensure professional development of team members.

Research outputs:

- Lead and contribute to scientific publications and research dissemination.
- Lead or significantly contribute to writing of grant proposals.

Qualifications and registration:

- Master's Degree in a Biomedical/Health related field (essential).
- Current registration with the Health Professions Council of South Africa, if applicable.
- Management qualification (essential).
- PhD in a Biomedical/Health related field (advantageous).
- Project Management qualification (advantageous).
- Valid GCP certification (advantageous).

Experience:

- Minimum of 5 years' experience managing clinical trials (essential).
- Minimum of 3 years demonstrated experience in clinical research site management and leading site research teams (essential).
- Comprehensive understanding of the current regulatory requirements pertaining to clinical trials (essential).
- Experience with regulatory submissions to SAHPRA, Ethics Committees, and other regulatory authorities (essential).
- Study trial document development including protocols, case report forms, and SOPS.
- Contribution to scientific publications and grant proposals.

Additional requirements:

- Proficiency in reading, speaking, and writing English.
- Proficiency in reading, speaking, and writing Xhosa (advantageous).
- Proficiency in Microsoft Office.
- Embracing and leveraging Artificial Intelligence (AI), to enhance operational efficiency.
- Willingness to work reasonable flexible hours, including weekends, if required, in accordance with the BCEA.
- Valid driver's license (essential).

Application process:

Interested candidates should apply by accessing the following link:

https://vacancies.fpdsiu.co.za/

Closing date for applications: 8 October 2025 at 16h00

The Foundation for Professional Development fosters a diverse and inclusive workplace. We invite and encourage qualified candidates with disabilities to apply for positions within our organisation. In line with the company's Employment Equity Plan, preference will be given to suitably qualified male candidates from designated groups.

Please note: Only shortlisted applicants will be contacted. If you have not been contacted within four weeks after the closing date of this advertisement, please accept that your application was unsuccessful. The company reserves the right not to make an appointment.